Premarket Approval (PMA) Package for Dockets Management Branch

PMA Number P990014
Docket # 99M-5135

Bausch & Lomb Surgical, Inc.
Hydroview Composite Hydrogel Foldable UV-Absorbing Posterior Chamber Intraocular Lens

Includes:

Approval Order
Summary of Safety and Effectiveness Data (SSED)
Labeling

99M-5135

AAV1

APPROVAL ORDER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Sharon D. Bishop
Regional Manager, Americas
Global Regulatory Affairs
Bausch & Lomb Surgical
21 Park Place Blvd. N.
Clear-water, FL 33759

NOV 12 1999

Re: P990014
Hydroview® Composite Hydrogel Foldable Ultraviolet-Absorbing Posterior Chamber Intraocular Lens, Model H60M
Filed: March 4, 1999
Amended: May 20 **and** 28, June **4,** August 31, September 27, and November 1 and 9, 1999

Dear Ms. Bishop:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Hydroview® Composite Hydrogel Foldable Ultraviolet-Absorbing Posterior Chamber Intraocular Lens, Model H60M. This device is indicated for for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed by extracapsular extraction methods. The lens is intended for placement in the capsular bag. We are pleased to inform you **that** the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with **21** CFR **801.109** within the meaning of section 520(e) of the Federal Food, Drug, and 'Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections **502(q)** and (r) of the act.

CDRH approval is subject to full compliance with the conditions described in the enclosure and the following:

1. Registration of all patients receiving the above-referenced intraocular lens must be continued and the data base shall be maintained indefinitely, or until the applicant is otherwise notified.

2. A way of facilitating adverse reaction reporting, such as an 800 telephone number, must be maintained.

3. FDA notes your agreement that you will continue postoperative follow-up for three years on 300 subjects derived from the core subjects to assess further the long-term safety and effectiveness of hydrogel IOLs. At the completion of the postapproval study, you must submit the clinical data and update your labeling accordingly.

4. Advertising and other printed materials prepared by your firm or its distributors will not include indications or claims not included in the FDA-approved labeling for the device, e.g., that the use of this lens (or that small incision surgery) results in more rapid visual recovery, decreased surgically-induced astigmatism, improved overall quality of vision, or similar claims.

Expiration dating for this device has been established and approved at 2 years. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(8).

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based.

The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number.

Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. As part of our reengineering effort, the Office of Device Evaluation is piloting a new process for review of final printed labeling. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment. Please see the CDRH

Pilot for Review of Final Printed Labeling document at http://www.fda.gov/cdrh/pmat/pilotpmat.html for further details.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Ms. Susanna Jones at (301) 594-2053.

Sincerely yours,

Philip J. Phillips
Deputy Director for Science and
Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 3-4-98

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CER 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

?OSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1)Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a)unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b)reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1)A mix-up of the device or its labeling with another article.

(2)Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a)has not been addressed by the device's labeling or

(b)has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3)Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984. This regulation was replaced by the reporting requirements of the Safe Medical Devices Act of 1990 which became effective July 31, 1996 and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to the FDA whenever they receive or otherwise become aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer or importer:

(1)May have caused or contributed to a death or serious injury; or

(2)Has malfunctioned and such device or similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same *events* subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for a PMA, the manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) usinq FDA Form 3500A, i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer is responsible for submitting a baseline report on FDA Form 3417 for a device when the device model is first reported under 21 CFR 803.50. This baseline report is to include the PMA reference number. Any written report and its envelope is to be specifically identified, e.g., "Manufacturer Report," "5-Day Report," "Baseline Report," etc.

Any written report is to be submitted to:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
PO Box 3002
Rockville, Maryland 20847-3002

Copies of the MDR Regulation (FOD # 336&1336)and FDA publications entitled "An Overview of the Medical Device Reporting Regulation" (FOD # 509) and "Medical Device Reporting for Manufacturers" (FOD #987) are available on the CDRH WWW Home Page. They are also available through CDRH's Fact-On-Demand (F-O-D) at 800-899-0381. Written requests for information can be made by sending a facsimile to CDRH's Division of Small Manufacturers Assistance (DSMA) at 301-443-8818.

SUMMARY OF SAFETY AND EFFECTIVENESS DATA (SSED)

SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. GENERAL INFORMATION

A. Premarket Approval Application (PMA) Number: P990014
Date Filed: March 4, 1999
Date Approved:

B. Generic Name of Device: Posterior Chamber Intraocular Lens (IOL)

C. Trade Name of Device: Hydroview ® Composite Hydrogel Foldable W-Absorbing Posterior Chamber Intraocular Lens, Model H60M

D . Applicant's Name and Address: Bausch & Lomb Surgical, Inc.
21 Park Place Blvd., N.
Clear-water, FL 33759

E. Good Manufacturing Practice (GMP) Inspection Date: September 12, 1997
Conclusion: The manufacturing site was found to be in compliance with device GMP requirements.

F. Ophthalmic Devices Panel (Panel):
Date Reviewed: July 23, 1999
Recommendation: Approvable

II. INDICATIONS

Bausch & Lomb Hydroview ® Composite Hydrogel Foldable W-Absorbing Posterior Chamber Intraocular Lens – Model H60M, is indicated for primary implantation for the visual correction of aphakia in patients 60 years of age or older where a cataractous lens has been removed by extracapsular extraction methods. The lens is intended for placement in the capsular bag.

III. SUMMARY

The applicant has performed nonclinical and clinical testing on the device, following the recommendations in the draft FDA guidance testing for intraocular lenses dated October 10, 1997. Data on 387 patients followed postoperatively for 12 months were evaluated against historical controls (Stark WJ, et al . 1983. The FDA Report on Intraocular Lenses. Ophthalmology 90(4): 3 1 l-317).

The population at risk for developing visually disabling cataracts and needing cataract surgery is typically elderly; the elderly population has a slightly higher proportion of females to males. The average age of the 387 cohort subjects was 74.3 years at the time of surgery; approximately 63% of the 387 cohort subjects were female and 37% were male. The inclusion / exclusion criteria did not exclude patients on the basis of gender or gender-related pathology The cohort study population of 387 patients was

96.4% Caucasian, 2.3% Black, and **1.3%** other. This study, which began in 1995, included all patients who met the inclusion criteria.

Based on the analysis of the detailed data presented in the PMA, it was determined that the clinical performance of this device, i.e., adverse events and visual acuity results, compares favorablywith FDA's 1983 grid of historical data.

Most Hydroview ® patients achieved a visual acuity of 20/40 or better. The rates for both overall and best-case visual acuity for both genders exceeded FDA grid values.

IV. SAFETY AND EFFECTIVENESS DATA

A. Nonclinical Studies

The applicant conducted a battery of in-vivo and in-vitro acute and chronic toxicity tests that establish the biocompatibility of the lens materials. These studies, combined with data from chemistry and engineering analyses, demonstrate the suitability of the material for use in intraocular lenses. The adequacy of the manufacturing processes, including sterilization, was established through a review of the manufacturing information in the PMA as well as thorough on-site inspections. Non-clinical testing demonstrates the safety and effectiveness of this device from microbiology, toxicology, engineering, and manufacturing perspectives.

B. Clinical Studies

Visual Acuity (% 20/40 or better)	Model H60M		Grid
Age			
≤ 59	100.0%	[7/7]	93.7%
60-69	95.7%	[89/93]	90.8%
70-79	99.3%	[147/148]	88.6%
280	91.6%	[76/83]	75.2%
All Cases, A.8 Ages	96.4%	[319/331]	88.0%
Best Case, All Ages	98.9%	[269/272]	94.0%
Cumulative Adverse Events			
Endophthalmitis	0.0%	0	<0.1%
Hyphema	0.3%	1	1.0%
Hypopyon	0.0%	0	0.4%
Lens Dislocation	0.0%	0	0.4%
Macular Edema	2.6%	10	3.5%
Pupillary Block	0.0%	0	0.3%
Retinal Detachment	0.0%	0	0.5%
Lens Epithelial Ongrowth (Anterior Surface)	1.0%	8	
Secondary Surgical Intervention	0.3%	1	2.0%
• Iridectomy for Pupillary Block	0.0%	0	
• Vitreous Aspiration for Pupillary Block	0.0%	0	
• Repositioning of Lens	0.0%	0	
• IOL Removal For Inflammation	0.0%	0	
• IOL Replacement	0.0%	0	
• Other (Not Lens Related)	0.3%	1	

Persistent Adverse Events			
Corneal Edema	0.0%	0	0.6%
Hyphema	0.0%	0	1.0%
Iritis	0.3%	1	1.0%
Macular Edema	0.0%	0	0.8%
Secondary Glaucoma	0.0%	0	0.5%
Vitritis	0.0%	0	0.1%
Lens Epithelial Ongrowth (Anterior Surface)	0.6%	6	

V. CONCLUSION

The Center for Devices and Radiological Health (CDRH) and the Panel reviewed the PMA and concluded that the PMA contained sufficient valid scientific evidence to provide reasonable assurance of the safety and effectiveness of the device under the prescribed indications for use. CDRH approved this PMA in a letter to the PMA applicant dated NOV 12 1999 and signed by the Deputy Director for Science and Regulatory Policy, Office of Device Evaluation.

LABELING

BAUSCH & LOMB Surgical | CHIRON VISION | storz

HYDROVIEW® COMPOSITE HYDROGEL FOLDABLE UV- ABSORBING - POSTERIOR CHAMBER INTRAOCULAR LENSES

PRODUCT INFORMATION,

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Device Description

Hydroview foldable ultraviolet absorbing posterior chamber intraocular lens& manufactured by Bausch & Lomb Surgical, Inc. are optical implants for the replacement of the human crystalline lens in the visual correction of aphakia.

The lenses are lathe cut and polished from a composite material. The foldable optic is cut from the central hydrogel portion which contains a bonded UV absorber. The haptics appear blue and are formed from the outer polymethylmethacrylate (PMMA) portion.

The optical portion is designed for folding prior to insertion. In the preapproval clinical study, 95.9% of Hydroview® lenses were inserted through an incision of 3.3 to 4.6 millimeters (mm).

The labeled dioptric power of the lens is in aqueous. The lens has an index of refraction of 1.474; a specific gravity of 1.19: and a transmission of visible light of 90%.

UV TRANSMISSION

[standard curve to be inserted here]

WAVELENGTH (NANOMETERS)

Human Lens 10 Diopter Lens 30 Diopter Lens

Hydroview intraocular lenses are supplied sterile. The pouch and vial are terminally sterilized and should be opened only under sterile conditions.

Mode of Action

When implanted, the Mydroview intraocular lens functions as a refracting medium to replace the natural lens in the visual correction of aphakia.

Indications

Hydroview posterior chamber lenses are indicated for primary implantation for the visual correction of aphakia in patients 60 years of -age or older where a cataractous lens has been removed by extracapsular extraction methods, The lens is designed far implantation in the capsular bag following extracapsular cataract extraction.

Warnings

- Physicians considering lens implantation under any of the following circumstances should weigh the potential risk/benefit ratio:
  1. Recurrent severe anterior or posterior segment inflammation or uveitis.
  2. Patients in whom the intraocular lens may affect the abifity to observe, diagnose, or treat posterior segment diseases.
  3. Surgical difficulties at the time of cataract extraction which might increase the potential for complications (e.g., persistent bleeding, significant iris damage, uncontrolled positive pressure, or significant vitreous prolapse or loss).
  4. A distorted eye due to previous trauma or developmental defect in which appropriate support of the IOL is not possible.
  5. Circumstances that would result in damage to the endothelium during implantation.
  6. Suspected microbial infection.
  7. Children under the age of 2 years are not suitable candidates for intraocular lenses.
  8. Patients in whom neither the posterior capsule nor zonules are intact enough to provide support,
- Since the clinical study for Hydroview was conducted with the lens being implanted in the capsular bag only, there are insufficient clinical data to demonstrate its safety and efficacy for placement in the ciliary sulcus.
- Improper handling or folding techniques may cause damage to the haptic or optic portions of Hydroview foldable lenses. If lenses are not folded according to directions, optic tears may result (see “Instructions for Use’;). Physicians should not attempt to implant lenses that have radial optic tears or separations at the optic/haptic interface.
- Use of folding instruments other than those validated and recommended in the labeling might result in IOL damage (optic tears, haptic breaks) that might require IOL explant&ion. In the preapproval clinical studies, haptic breaks (1.6%) and optic tears (1%) occurred using the original packaging

(amber-colored holder). No haptic breaks or optic tears were observed in the clinical study using the Surefold system.

- To avoid the creation of permanent forcep marks in the central optic zone, exercise care during handling and insertion of the lens. In the preapproval clinical study, permanent forcep marks were observed in 3.1% of cases. Read and follow the folding and insertion instructions carefully.

Precautions

1. Do not attempt to resterilize these lenses.
2. 00 not store the lens in direct sunlight or at temperatures below freezing.
3. Do not soak or rinse lenses in solutions other than balanced saft solution or equivalent.
4. A surgeon should have observed and/or assisted in numerous surgical implantations and should have completed one or more courses on intraocular lens implantation before attempting to implant intraocular lenses.
5. The physician should have reviewed all instructional materials provided by Bausch 8 Lomb Surgical, Inc. for proper handling and insertion of Hydroview lenses before attempting to implant these lenses.

Reporting

Adverse reactions and/or potentially sight threatening complications that may reasonably be regarded as lens related and that were not previously expected in nature, severity or degree of incidence should be reported within five (5) days to Bausch & Lomb Surgical. Inc., Clearwater, Florida, at the toll-free number. This information is being requested from all implant surgeons in order to document potential long-term effects of intraocular lens implantation.

- Physicians are encouraged to report these events in order to aid in identifying emerging or potential problems with intraocular lenses. These problems may be related to a specific lot of lenses or may be indicative of long-term effects associated with these lenses or with IOLs in general.
- If the patient has a Bausch & Lomb Surgical intraocular lens and you wish to report, please call:

Bausch & Lomb Surgical, Inc.
1-(800) 252-7890
Local (727) 724-6600

Calculation of Lens Power

The physician should determine preoperatively the power of the intraocular lens to be implanted. Lens power calculation methods are described in the references listed in the bibliography at the end of this insert. Alternately, physicians requiring additional information on lens power calculation may contact Bausch 8 Lomb Surgical, Inc., Clearwater, Florida.

How Supplied

Hydroview foldable intraocular lenses are supplied STERILE in a hydrated state, in a glass vial which is enclosed in a sterile autoclaved pouch, and should be opened only under sterile conditions (see section "Directions For Use").

Expiration Date

The expiration date on the lens package is the sterility expiration date. Any lens held after this date should be returned to Bausch & Lomb Surgical, Inc., Clearwater, Florida 33759.

Warranty

Bausch & Lomb Surgical, Inc. warrants that its" IOL products conform to all applicable laws and that they will *perform* as represented.

BAUSCH & LOMB SURGICAL, INC. DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN THOSE EXPRESSLY SET FOR THE IN THE PRODUCT LABELING. IN NO EVENT WILL BAUSCH & LOMB SURGICAL, INC. BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGE IN CONNECTION WITH THE PURCHASE OR USE OF ITS PRODUCTS.

Return Goods and Resterilization Policy

All lenses being returned must be accompanied by an authorization number issued by Bausch & Lomb Surgical Customer Service. Opened or unopened lenses will be exchanged for a comparable dollar value, provided they have not exceeded their expiration date. A reprocessing charge may be assessed for lenses which have exceeded their expiration date. This applies to opened or unopened lenses. It is not Bausch & Lomb Surgical policy to issue credit or cash refunds for returned lenses.

Instructions for Use

Note: To avoid dehydration, leave lens Immersed in vial until ready to fold and Implant. The lens should be folded within 3 minutes after removal from vial.

Note: In the preapproval clinical study, 95.9% of Hydroview® lenses were inserted through an incision of 3.3 to 4.6 millimeters (mm).

1. In a sterile environment, peel open the pouch to present the sterile vial.
2. Twist and remove screw cap. Remove folding mechanism from vial. The lens is contained within the mechanism.
3. Remove the lens retainer by gently rotating the retainer counterclockwise until it stops (about a 25 degree turn), and then lifting (Reference Fig. 1 and 2). Do not squeeze the folder while removing the retainer.
4. Figure 3 shows an unfolded lens seated in the folder.
5. Fold lens by squeezing two halves of the holder between the thumb and fore-finger (Reference Fig. 4).

6. Grasp the folded optic as close as possible to the folder with smooth-edged insertion forceps. The forceps should be completely clean and free of all particulate matter. Release the pressure on the folder. The superior haptic should be between fhe smooth-edged forceps' prongs (Reference Fig. 5 and 6).
7. Thoroughly rinse lens with BSS solution.
8. During insertion, the haptic tip should point to the surgeon's left and should enter the incision first in the orientation shown (Reference Fig. 6). The inferior haptic should first be placed beneath the anterior capsular rim. The forceps should be rotated clockwise and opened slowly. The superior haptic will rota& outside of the eye. Once the lens has unfolded, introduce the superior haptic into the capsular bag in a fashion similar to a conventional lens.
   Note: To avoid damage, do not expand the haptics, flex the haptics out of the plane of the lens, or twist or torque the lens. Possible damage includes tearing the optic, damaging the optic/haptic interface or breaking the haptic.

Alternative Folding Techniques

Note: To avoid scratching the lens, alternate folding techniques should not be used for lenses higher than 27 diopters in power.
Note: All folding instruments should be completely clean and free of all particulate matter.

- Osher-Seibel Folding instrument (E2976) - After removing the lens from the holder, place the lens in a petri dish with BSS solution. The anterior side of the lens should be facing up. Grasp the lens at the 3 and 9 o'clock positions with the Osher-Seibel folder (Reference Fig. 7). Fold the lens by squeezing the forceps while keeping the lens against the bottom of the petri dish. Continue with step 6 above.

*Bausch & Lomb Surgical Hydrofolder (2-778) - After removing the lens from the holder and rinsing with BSS solution, insert the lens into the holder by sliding it above the two support plates and into the grooves located on thh inside arms of the folder. Insert the lens until the leading haptic reaches the notch located on the instrument arm (Reference Fig. 8). Squeeze the folding instrument until the haptics are in the vertical position. Continue with step 6 above.

Note: The recommended folding technique is to fofd the lens along the 6 to 12 o'clock axis, with a maxfmum deviation of 10 degrees counterclockwise (Reference Fig. 9). Do not fold Hydroview® lenses along the 3 to 9 o'clock axis. Folding along any other axis may cause damage to the optic or haptics.

Patient Registration Instructions

Bausch & Lomb Surgical has a patient registration system in order to contact physicians or patients if unrecognized long-term effects of the lenses ads discovered. The lens package contains product identification stickers for maintaining a record of lens usage and patient registration. At the time of surgery, the prepaid implant registration card included in the package is to be completed and returned to Bausch & Lomb Surgical, Inc., Clearwater, Florida, It is critical that all patients be registered.

An implant identification card to be supplied to the patient is also included in the package. Patients should be instructed to keep the card as a permanent record of their implant, and should also be instructed to show the card to any eye practitioner consulted in the future.

Clinical Experience

Clinical trials of the Hydroview® Model H60M posterior chamber lens began in January 1995. The data presented for the Hydroview® clinical trial represents the experience of 387 patients successfully followed throughout one year of postoperative study. The results achieved indicate that Hydroview® (H60M) posterior chamber intraocular lenses with UV absorber are safe and effective for the visual correction of aphakia. The patient population in the clinical trials consisted of 63.3% females and 36.7% males. Of this population, 96.4% were Caucasian, 2.3% were black, 1.3% other. The mean age for the total population was 74.2 years.

Visual Acuity

The following is a summary of visual acuity reported at 12-14 month postoperatively by subjects who did not have preoperative ocular pathology, abnormal corneas or postoperative macular degeneration (Best Case). The table compares the results with the historical control, the Stark grid (Stark, W.J., et al,: 1983).

Table 1
Visual Acuity in Best Case Population (N =272)

Age	Cases N (%)	Visual Acuity 20/ 0-20 n (%)	21-30 n (%)	31-40 n (%)	>40 n (%)	Stark Grid Results 20/40 or better
<59	7 (2.6)	6 (85.7)	1 (14.3)	0 (0.0)	0 (0.0)	93.7%
60-69	82 (30.1)	56 (68.3)	25 (30.5)	0 (0.0)	1 (1.2)	90.8%
70-79	124(45.6)	67 (54.0)	48 (38.7)	9 (7.3)	0 (0.0)	88.6%
80+	59 (21.7)	30 (50.8)	26 (44.1)	2 (3.4)	1 (1.7)	75.2%
TOTAL	272 (100.0)	159(58.5)	100(36.8)	11 (4.0)	2 (0.7)	

Adverse Events

Cumulative adverse events include the total number of adverse events that have occurred at any time during the first postoperative year. The cumulative adverse events experienced during the clinical trial of Model H60M are listed in Table 2.

Table 2

Cumulative Adverse Event	H60M Incidence (%)	Stark Grid
	N = 387	
Macular Edema	2.6%	3.5%
Hyphema	0.3%	1.0%
Secondary Surgical Intervention TOTAL	0.3%	2.0%
• Iridectomy for Pupillary Block	0.0%	N/A
• Vitreous Aspiration for Pupillary Block	0.0%	N/A
• Repositioning of Lens	0.0%	N/A
• IOL Removal for Inflammation	0.0%	N/A
• IOL Replacement	0.0%	N/A
• Other (Per investigator, not lens related)	0.3%	N/A
Endophthalmitis	0.0%	<0.1 %
Hypopyon	0.0%	0.4%
Lens Dislocation	0.0%	0.4%
Pupillary Block	0.0%	0.3%
Retinal Detachment	0.0%	0.3%
Lens Epithelial Ongrowth (anterior surface)	1.0%	NA

Persistent adverse events are those present at the one-year postoperative visit. The persistent adverse events experienced during the clinical trial of Model H60M are listed in Table 3.).

Table 3

Persistent Adverse Event	H60M Incidence (%)	Stark Grid
	N = 332	
Iritis	0.3%	1.0%
Hyphema	0.0%	1.0%
Corneal Edema	0.0%	0.6%
Macular Edema	0.0%	0.8%
Secondary Glaucoma	0.0%	0.5%
Vitritis	0.0%	0.1%
Lens Ephithelial Ongrowth (anterior surface}	0.6%	NA

As of January, 1999, there were 782 H60M study implants and the overall incidence of adverse events is 2.7%.

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